REMARKS

This Amendment is responsive to the Office Action dated December 5, 2006. Applicant has amended claims 1, 2, 5-8, 10-23, 33 and 35-41; cancelled claims 3, 9 and 24-32; and added new claims 54-58. Claims 1, 2, 4-8, 10-23, 33-41, and 54-58 are pending, with claims 5-7, 15-17, and 35-37 withdrawn from consideration due to restriction.

Information Disclosure Statement

The Office Action indicated that the Information Disclosure Statement filed April 12, 2004 failed to comply with the provisions of 37 C.F.R. §§ 1.97 and 1.98 because two of the references cited therein had a publication year within a year of the filing date of the present application, but lacked a publication month. It appears that the Examiner is referring to the following references cited in the Information Disclosure Statement: (1) Khalessi, A. A., Taylor, R. S., Brigham, D. D., North, R. B., "Automated, patient-interactive spinal cord stimulator adjustment: A cost-minimization analysis," Neurosurgery, 53:501-502, 2003; and (2) North, R. B., Calkins, S. K., Campbell, D. S., Sieracki, J. M., Piantadosi, S. A., Daly, M. J., Dey, P. B., Barolat, G., "Automated, patient-interactive spinal cord stimulator adjustment: A randomized, controlled trial," Neurosurgery 52:572-580, 2003.

With this Amendment, Applicant resubmits the Information Disclosure Statement filed April 12, 2004. The Information Disclosure Statement has been corrected to include the publication months for the two above-identified references.

Claim Rejection Under 35 U.S.C. § 102

The Office Action rejected claims 1, 2, 4, 8, 10, 33, 34, 38 and 39 under 35 U.S.C. § 102(b) as being anticipated by Batty, Jr. et al. (US 4,550,732, herein referred to as "Batty"). Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims. Batty fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, with respect to amended independent claims 1 and 33, Batty fails to teach or suggest receiving stay-alive signals from a programming device at a watchdog unit coupled to the

programming device during a programming session between the programming device and an implantable medical device, resetting a watchdog timer maintained by the watchdog unit in response to receipt of each of the stay-alive signals, and sending a signal from the watchdog unit to the implantable medical device via wireless telemetry to change a mode of operation of the implantable medical device in response to expiration of the watchdog timer.

Instead, Batty describes an interrupt routine controlled by a microprocessor within an implanted pacer that determines when the pacer is in its programming state. Batty describes receiving pulse width modulated access and command signals at an implanted pacer and controlling operation of the implanted pacer based on the signals received. Upon receipt of an access command, a microprocessor within the implanted pacer can interrupt normal output functions (e.g., enter an interrupt routine) so that it can receive command signals.[1] Once an access code is accepted and a command code is received, the magnet mode (e.g., programming state) of the microprocessor will continue unless there is more than a four millisecond gap without any pulses. If there is no pulse activity for more than four milliseconds, the interrupt routine controlled by the microprocessor will return the system to its normal pacing routines.[2] Various functions performed by a microprocessor within the implantable medical device, as taught by Batty, would not have suggested a watchdog unit coupled to a programming device during a programming session between the programming device and an implantable medical device, as recited by claims 1 and 33.

Furthermore, Batty does not disclose or suggest sending a signal from the watchdog unit to the implantable medical device via wireless telemetry to change a mode of operation of the implantable medical device in response to expiration of the watchdog timer. Instead, Batty teaches that the microprocessor within an implanted pacer returns the implanted pacer to normal pacing routines if pulses are not received by the implanted pacer for more than four milliseconds. The microprocessor within the implanted pacer determines when to return to normal pacing routines. Since the microprocessor is located within the implanted pacer, the microprocessor does not use wireless telemetry to return the implanted pacer to normal pacing routines. The implanted pacer disclosed in Batty does not receive a signal from a watchdog unit via wireless

[1] Batty, column 4, lines 49-54.
[2] Batty, column 6, lines 42-65 and FIG. 7.

telemetry to change a mode of operation of the implantable medical device in response to expiration of a watchdog timer. For at least these reasons, Batty fails to disclose or suggest each and every element of independent claims 1 and 33.

Batty also fails to disclose or suggest a watchdog unit that is coupled to the programming device by a cable, as required by amended claim 2. Batty describes a microprocessor within an implanted pacer that controls when the pacer is in its programming state. Batty does not disclose or suggest a watchdog unit that is coupled to the programming device by a cable as required by Applicant's claim 2.

Batty fails to disclose each and every limitation set forth in independent claims 1 and 33. Claims 2, 4, 8, and 10 are dependent upon claim 1, and claims 34, 38, and 39 are dependent upon claim 33. These dependent claims are also in condition for allowance for at least the reasons stated previously with respect to independent claims 1 and 33. For at least these reasons, the Office Action has failed to establish anticipation of Applicant's claims 1, 2, 4, 8, 10, 33, 34, 38 and 39 under 35 U.S.C. § 102(b). Withdrawal of this rejection is requested.

Claim Rejections Under 35 U.S.C. § 103

The Office Action rejected claims 11, 12, 40 and 41 under 35 U.S.C. § 103(a) as being unpatentable over Batty; and rejected claims 13, 14 and 18-23 under 35 U.S.C. § 103(a) as being unpatentable over Batty in view of Grevious et al. (US 5,752,977, herein referred to as "Grevious"). Applicant respectfully traverses these rejections to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

With reference to independent claim 13, for example, the applied references lack any teaching that would have suggested a watchdog unit comprising a telemetry circuit and a processor to receive stay-alive signals from a programming device coupled to the watchdog unit during a programming session between the programming device and an implantable medical device, reset a watchdog timer in response to receipt of each of the stay-alive signals, and send a signal to the implantable medical device via the telemetry circuit to change a mode of operation of the implantable medical device in response to expiration of the watchdog timer.

The Office Action acknowledged that Batty fails to disclose or suggest sending a signal to the implanted pacer via the telemetry circuit to change a mode of operation of the implanted pacer in response to expiration of the watchdog timer. However, the Office Action reasoned that it would have been obvious to modify the system of Batty to instruct the implanted pacer to change a mode of operation of the pacer via telemetry in the event that an error is detected to ensure that the implantable medical device provides suitable therapy in spite a faulty telemetry transmission, as taught by Grevious.

Claim 13 requires that a signal is sent **via wireless telemetry in response to expiration of the watchdog timer**. As discussed above, Batty describes a microprocessor within an implanted pacer that returns the implant to normal pacing routines if there is no pulse activity from an external programmer for more than four milliseconds. In rejecting Applicant's other independent claims, the Office Action relied on these teachings of Batty as meeting the requirements in those claims with respect to receiving stay-alive signals, resetting a watchdog timer, and changing a mode of operation of the implant in response to expiration of the watchdog timer. Accordingly, in rejecting independent claim 13, the Office Action appears to be arguing that it would have been obvious to modify Batty such that "another" external device in wireless communication with the implanted pacer performs the functionality formerly provided by the internal microprocessor of the pacer with respect to monitoring pulse activity from the external programmer, and changing a mode of the implanted pacer if there is no pulse activity from the external programmer for more than four milliseconds.[3] This "other device" in the proposed modification performs the mode changing functionality formerly provided by the internal microprocessor by sending a signal to the implanted pacer via wireless telemetry.

[3] Modification of Batty such that the mode changing is performed by an external device via wireless telemetry requires modification such that the external device also monitors the pulse activity. It would be nonsensical to suggest that the internal microprocessor monitors pulse activity, but that a signal to change the mode of the implant in response to failure of the pulse activity somehow comes from another device via wireless telemetry. Furthermore, the "other" device must be different from the external programmer disclosed by Batty, as it would make no sense in the context of the Batty invention for the external programmer itself to monitor whether it sending pulses. The programmer itself monitoring whether it is sending pulses would frustrate the stated purpose of the Batty invention.

There is no teaching in Grevious that would have motivated a person of ordinary skill to modify the Batty system in this manner. Grevious describes an external programmer that interrupts the uplink between the external programmer and the implantable pulse generator and instructs the pulse generator to reduce or eliminate the use of a pulse width modulation feature for uplink communication with the external programmer if the uplink signal strength is low or the noise level is high.[4] The use of the pulse width modulation feature is altered in response to error detection circuitry within the external programmer determining that the signal strength is low or the noise level is high. In other words, Grevious describes an external programmer that monitors the quality of uplink communications received at the external programmer, and instructs the implant to use a different communication technique if the communications are of low quality. The teaching in Grevious of a programming device that monitors uplink signals from an implant and sends communication mode changing signals to the implant based on the quality of uplink signals, would not have suggested modification of the Batty system to include "another" external device that monitors pulses sent from an external programmer to the implant, and sends a mode-changing signal to the implant via wireless telemetry based on failure of the pulses from the external programmer.

Additionally, with respect to claims 11, 12, 40, and 41, the Office Action acknowledged that Batty fails to disclose or suggest the features of these claims. However, the Office Action concluded that modification of Batty to include the elements of claims 11, 12, 40, and 41 would have been obvious.

The Office Action provided no evidentiary support for these conclusions. Instead, the Office Action argued that it is well-known in the art to: (1) change a mode of operation based on an emergency off from a user to allow a patient to suspend therapy based on physiological condition or device malfunction; (2) to utilize telemetry features, such as watchdog timers, in neurostimulators to provide easy and reliable communication with these implanted devices; and (3) to detect power delivery failure, activate auxiliary power, and change the mode of operation in response to detection to provide an implantable medical device with a constant source of power. Applicant respectfully traverses these findings of allegedly well-known facts. Applicant

[4] Grevious, column 11, lines 41-45.

respectfully submits that these alleged facts, asserted to be well known, are not capable of instant and unquestionable demonstration as being well-known in the art. Applicant respectfully requests that any subsequent action include documentary evidence or an affidavit supporting these allegedly well-known facts.

Furthermore, even if these allegedly well-known teachings were in fact known in the art, the Office Action also failed to provide any ***evidence*** with respect to why one of ordinary skill in the art would have been motivated to modify Batty based on the allegedly well-known teachings. The Office Action relied on statements of motivation (e.g., "allow a patient to suspend therapy based on patient condition or device malfunction," "easy and reliable communication," and "constant source of power") unsupported by any documentary evidence in the record.

The Federal Circuit has stated: "[the] factual question of motivation is material to patentability, and (can) not be resolved on subjective belief and unknown authority.[5] This finding must be based upon substantial evidence, and not subjective musings or conjecture by the Examiner.[6] Deficiencies in the evidentiary record cannot be cured by general conclusions such as "general knowledge" or "common sense."[7] Accordingly, the Examiner cannot rely on unsupported, conclusory statements to close holes in the evidentiary record.[8] Unless the Examiner can establish an evidentiary record based on concrete prior art references that establish that it would have been obvious to a person with ordinary skill in the art to incorporate the features of Applicant's dependent claims, the claims should be allowed.

For example, with respect to claims 11, 12, 40, and 41, the Office Action stated that the features of these claims are well-known in the art and reasoned that it would be obvious to one of ordinary skill in the art to modify of the system of Batty to include the elements of claims 11, 12, 40, and 41. The Examiner has not even provided a reference that substantiates the existence of such a feature in other systems at the time of Applicant's filing, much less evidentiary support of motivation to combine this feature into the systems of the applied references. At a bare minimum, Applicant must be afforded an opportunity to rebut any evidence, if such evidence

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[5] *Id.* at 1434.
[6] *Id.*
[7] *Id.*
[8] *Id.*

exists. The current evidentiary record, however, does not even provide Applicant with that opportunity.

Furthermore, with respect to claims 22 and 23, the Office Action reasoned that it would have been an obvious matter of design choice to one or ordinary skill in the art to position a watchdog unit within a programming head or couple a watchdog unit to a programming head via a cable. This mere assertion of "design choice" clearly does not meet the evidentiary standards set forth in the above-discussed Federal Circuit decisions. The current evidentiary record does not in any way support the assertion that it would be a matter of design choice to move the pulse monitoring functionality provided by the internal microprocessor of the Batty implant into an external programming head.

For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 11-14, 18-23, 40, and 41 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

New Claims:

Applicant has added claims 54-58 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. As one example, the references fail to disclose or suggest a system comprising a programming device, an implantable medical device, and a watchdog unit coupled to the programming device to receive stay-alive signals from the programming device during a programming session between the programming device and the implantable medical device, reset a watchdog timer maintained by the watchdog unit in response to receipt of each of the stay-alive signals, and send a signal from the watchdog unit to the implantable medical device via wireless telemetry to change a mode of operation of the implantable medical device in response to expiration of the watchdog timer. No new matter has been added by the new claims.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 4/4/07

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